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211

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| 09/491,549      | 01/26/00    | BAULCOMBE            | D                   |

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SUITE 720  
1601 MARKET STREET  
PHILADELPHIA PA 19103-2307

EXAMINER

PARAS JR, P

| ART UNIT | PAPER NUMBER |
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1632

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DATE MAILED: 01/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/491,549

Applicant(s)

BAULCOMBE ET AL.

Examiner

Peter Paras

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 3-4, 18-20, 22-25, and 30-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-17, 21, 26-29 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1, 5-7, 12-17, to be examined with respect to the elected species of plant (claims 2, 21, and 26-29) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the Examiner has not shown that a serious burden would be required to examine all the claims. In particular, Applicants submit that it would not have been undue to search the claims of Group I and Group II, since they are both directed to similar subject matter. This is not found persuasive because it is maintained that each of the Inventions requires a separate search status. In particular, Groups I and II are directed to different methods that require materially different reagents and technical considerations and are thus, separately classified and searched. The requirement is still deemed proper and is therefore made **FINAL**.

Please note that after a final requirement for restriction, the Applicants, in addition to making any response due on the remainder of the action, may petition the Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested. (See § 1.181.).

However, **please note that as per Applicants' request, two Groups will be examined which are not thought to place an undue search burden upon the Examiner. As such Groups I (claims 1, 5-7, 12-17, 32) and II (claims 8-11) will be examined in this instant Office action. New claim 32 will be examined as part of Group I.**

Claims 1-32 are pending, however, claims 3-4, 18-20, 22-25, and 30-31 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions, the requirement having been traversed in Paper No. 8.

### ***Claim Objections***

Claim 14 is objected to because of the following informalities: the word "hybridization" is misspelled.

Claim 26 is objected to because of the following informalities: The word "one" is misspelled.

Claim 21 is objected to because of the following informalities: claim 21 depends from a nonelected claim. Appropriate correction is required.

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Great Britain on 10/27/99. It is noted, however, that applicant has not filed a certified copy of the British application as required by 35 U.S.C. 119(b).

### ***Specification***

Applicant is reminded of the proper language and format for an abstract of the disclosure. Appropriate correction is required.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract

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on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 5-11, and 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5-8, 11, and 16-17 are indefinite as written. The term "short RNA molecules which are approximately 25 nucleotides in length (SRMs)" is not clearly defined as written in the claim. The term "approximately " is a relative term which does not have a definite meaning and renders the claims indefinite. Correction is required. Claim 2 depend from claim 1. Claims 9-10 depend from claim 8.

**Note, the elected claims must be amended to be directed to the elected species-plant.**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 5-17, 21, 26-29, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waterhouse et al (PNAS, 1998, 95: 13959-13964) taken with Wassenegger et al (Plant Mol. Biol., 1998, 37: 349-362).

Claims 1-2 and 5-7 are directed to a method of determining the occurrence of target gene silencing in an organism, particularly a plant, wherein the presence of short RNA molecules (SRMs) that are approximately 25 nucleotides in length correlates with the occurrence of gene silencing, wherein the SRMs are antisense or sense RNA molecules. Claims 8-10 are directed to a method of detecting a silenced target gene in an organism by detecting and characterizing SRMs. Claim 11 is directed to a method of identifying a silenced target gene by characterizing any detected SRMs and identifying those genes that share sequence homology with the detected SRMs. Claims 12-16 are directed to a process for isolating one or more RNA molecules associated with target gene silencing from a sample comprising isolating and purifying said RNA molecules, separating said RNA molecules on a gel, transferring said RNA molecules to a

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hybridization membrane, and labeling said RNA molecules on said membrane with a radioactive probe. Claim 17 is directed to a process for isolating a silencing agent comprising SRMs for a target gene comprising the method of claim 16. Claims 21 and 32 are directed to a method of determining silencing of a target gene, wherein particular classes of genes are silenced. Claim 26-29 are directed to a method of silencing a target gene in an organism wherein a DNA construct that is introduced into the same organism results in silencing of a target gene.

Waterhouse et al teach posttranscriptional gene silencing (PTGS) using constructs that form double stranded mRNA. Waterhouse et al identify RNA molecules that silence the Pro gene of potato virus Y (PVY) by Northern blot analysis. See figures 3 and 5, and Materials and Methods section. Waterhouse et al do not teach SRMs that are approximately 25 nucleotides in length. However at the time the claimed invention was made, Wassenegger et al teach that 43 nucleotide long element was highly complementary to a part of the coding region of the chalcone synthase gene; base pairing of the complementary regions form double-stranded RNA which are then degraded. See page 351, column 1, paragraph 1. Wassenegger et al also suggest that (PTGS) homology of 60 to 130 bp or 10-100 bp between an inactivating transgene and the target sequence can lead to PTGS. See page 356.

Accordingly, in view of the teachings of Wassenegger et al, it would have been obvious for one of ordinary skill in the art, at the time the invention was made, to modify the teachings of Waterhouse et al by identifying small RNA molecules, by Northern blot analysis, that can silence a gene, with a reasonable expectation of success. One of

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ordinary skill in the art would have been motivated to make such a modification as it was an art-recognized goal to elucidate the mechanism of PTGS as taught by both Waterhouse et al (page 13964 final two paragraphs) and Wassenegger et al (page 356).

Thus, the claimed invention, as a whole, is prima facie obvious in the absence of any evidence to the contrary.

### **Conclusion**

**No claims are allowed.**



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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached at 703-305-6608. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Kay Pinckney whose telephone number is (703) 305-3553.

Peter Paras, Jr.

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JILL D. MARTIN  
PATENT EXAMINER  
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